1950022

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date · MAY 10 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Ventritex®, Inc.
TVL® Lead System - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D. M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by JDonelson, CDRH, HFZ-450, 301 443-8320
Dterry (SSED), CDRH, HFZ-450, 301 443-8609

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. _____]

Ventritex, Inc.; Premarket Approval of the TVL® Lead System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Ventritex, Inc., Sunnyvale, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the TVL® Lead System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 10, 1996, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Doris Terry,

Center for Devices and Radiological Health (HFZ-450),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-594-8609.

SUPPLEMENTARY INFORMATION: On June 30, 1995, Ventritex, Inc., Sunnyvale, CA 94086-6527, submitted to CDRH an application for premarket approval of the TVL® Lead System. The TVL® Lead System is indicated for use with commercially available pulse generators with which it has been tested. The TVL® Lead System is a transvenous defibrillation lead system and is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with an acute myocardial infarction or have ventricular tacharrhythmias. In addition, the TVL® Lead System can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the connected pulse generator provide therapy back-up in the event that the arrhythmia accelerates.

In accordance with the provisions of section 515(c)(2) of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Advisory Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On May 10, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act,(21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review

will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Sweeney
Vice President, Clinical Engineering
Ventritex, Inc.
709 East Evelyn Avenue
Sunnyvale, California 94086-6527

MAY 10 1996

Re: P950022
TVL® Lead System
Filed: June 30, 1995
Amended: January 4 and February 1 and 16, March 12, 20, and 26, and April 23 and 29, and May 6, 1996

Dear Mr. Sweeney:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Ventritex TVL® Lead System. The TVL® Lead System consists of the following: the Transvenous Right Ventricular Lead Models RV-1101, RV01, and RV02; Transvenous Superior Vena Cava Lead Models, SV-1101, SV01, SV02 and SV03; Subcutaneous Lead Models, SQ-701 and SQ01; Vein Pick Model TV-0001; Silicone Lubricant Model TV-0013; Lead Tunneler Kit Model LTK-01; Model AC-2481 High Voltage Y-Adapter; Model AC-CDT-EX Ventritex External Stimulator Adapter; and TVL® Lead System Accessory Kit. The TVL® Lead System is used with commercially available pulse generators with which it has been tested. The TVL® Lead System is a transvenous defibrillation lead system and is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with an acute myocardial infarction or have ventricular tachyarrhythmias. In addition, the TVL® Lead System can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the connected pulse generator provide therapy back-up in the event that the arrhythmia accelerates.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval for Implantable Defibrillators and Programmers" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the

6

training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at 3 years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

In addition under section 522(a) of the act, manufacturers of certain types of devices identified by the act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under section 522(a)(1)(A) the above noted device as requiring postmarket surveillance.

Upon approval and within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you will be required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is enclosed.

At that time you should submit five (5) copies to:

Postmarket Studies Document Center
1350 Piccard Drive (HFZ-544)
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. Do not undertake a postmarket surveillance study without an FDA approved protocol.

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol, will be considered violations of section 522.

In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) the act, (21 U.S.C. 331(q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties or other FDA enforcement actions including (but not limited to) withdrawal of your PMA.

If you have any questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch, at (301) 594-0639.

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have questions concerning this approval order, please contact Doris Terry at (301) 443-8609.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

Device Generic Name:	Transvenous Defibrillation Lead System
Device Trade Name:	TVL® Lead System
Applicant's Name and Address:	Ventritex® Inc. 709 E. Evelyn Avenue Sunnyvale, CA 94086-6527
Premarket Approval (PMA) Application Number:	P950022
Date of Panel Recommendation:	Not Applicable
Date of Notice of Approval to Applicant:	MAY 10 1996

II. Indications for Use

The TVL® Lead System is indicated for use with commercially available pulse generators with which it has been tested. The TVL® Lead System is a transvenous defibrillation lead system and is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with an acute myocardial infarction or have ventricular tachyarrhythmias. In addition, the TVL® Lead System can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the connected pulse generator provide therapy back-up in the event that the arrhythmia accelerates.

III. Device Description

The TVL® Lead System consists of the following: Transvenous Right Ventricular Lead Models RV-1101, RV01, and RV02; Transvenous Superior Vena Cava Lead Models SV-1101, SV01, SV02, and SV03; Subcutaneous Patch Lead Models SQ-701 and SQ01; Vein Pick Model TV-0001; Silicone Lubricant Model TV-0013; Lead Tunneler Kit Model LTK-01 and its individual components {Tunneler Shaft Model LT-01; Blunt Dissection Tip Model LT-DT-01; RV/SVC Cartridge Model LT-RVC-01; SQ Cartridge Model LT-SQC-01}; High Voltage Y-Adapter Model AC-2481; Ventritex External Stimulator Adapter Model AC-CDT-EX; and TVL® Lead System Accessory Kit Model AC-TVL including individual components {Stylets Models S-45-R, S-45-F, S-55-R, S-55-F, S-67-R, S-67-F, S-100-R, S-100-F, S-110-R, S-110-F; Suture Sleeves Models TV-1100 and TV-0800; Lead Cap Model TV-3201}.

Various lead configurations are possible using the TVL® Lead System. As an example, the transvenous right ventricular (RV) lead can be used as the cathode with the transvenous superior vena cava (SVC) lead used as the anode. Alternatively, a "reversed polarity" configuration can be used, with the RV electrode as the anode and the SVC electrode as the cathode. If an additional electrode is necessary, a subcutaneous (SQ) patch lead can be added; the RV lead serves as the cathode and the SVC and SQ lead are used as a common anode. Alternatively, a second SVC lead positioned in parallel with the other SVC lead could be used instead of the SQ lead.

A. Right Ventricular Lead Models RV-1101, RV01, and RV02

The RV lead has two platinum-iridium electrodes: the proximal defibrillation coil and the distal pacing tip. For bipolar sensing and pacing, the pacing tip is used as the cathode and the defibrillation coil as the anode. The pacing tip has a diameter of 1.8 mm and an area of 6 mm^2. The defibrillation electrode is 3.0 mm in diameter and has an area of 470 mm^2. The lead conductors are in a multifilar coil configuration and are insulated with silicone rubber. The lead has one DF-1 connector and one IS-1 connector. The RV-1101 and RV-01 are 110 cm in length and the RV02 is 67 cm. The RV leads are packaged with the Vein Pick Model TV-0001, Silicone Lubricant Model TV-0013, suture sleeves, lead caps and both regular and firm stylets.

B. Superior Vena Cava Lead Models SV-1101, SV01, SV02, and SV03

The transvenous SVC lead is intended for intravascular implantation, typically with the distal tip positioned between the junction of the superior vena cava/right atrium and the innominate vein. It provides delivery of cardioversion/defibrillation shocks.

The lead has one platinum-iridium defibrillation coil electrode that is 2.4 mm in diameter and has an area of 550 mm^2. The lead conductor is in a multifilar coil configuration and is insulated with silicone rubber. The lead has one DF-1 connector. The maximum diameter of the lead is 2.7 mm; thus, the recommended lead introducer size is 8.5 French. The SV-1101 is 110 cm in length, the SV01 is 100 cm, the SVO2 is 45 cm and the SV03 is 55 cm. The SVC leads are packaged with Vein Pick Model TV-0001, Silicone Lubricant Model TV-0013, suture sleeves, a lead cap and both regular and firm stylets.

C. Subcutaneous Patch Lead Models SQ-701 and SQ01

The subcutaneous patch lead is intended for implantation on the chest wall, in conjunction with the RV lead, the SVC lead, or both. It is not intended for epicardial placement. The SQ patch can deliver cardioversion/defibrillation shocks when reliable arrhythmia conversion cannot be obtained using the transvenous leads alone or when an alternative configuration of leads is desired. The SQ patch may reduce the voltage required for successful tachyarrhythmia termination in some patients.

The lead is designed with a stiff reinforced silicone rubber backing to inhibit folding after implantation, and has a DF-1 connector. The platinum-iridium electrode has a surface area of 39 cm^2. The lead body is 70 cm in length. The SQ-701 and SQ01 are identical; the different model numbers reflect only a change in model number scheme. The SQ patch is packaged with the silicone lubricant named above, a suture sleeve, and a lead cap.

D. Lead Tunneler Kit Model LTK-01 and Components

The lead tunneler, the Model LTK-01, can be used to tunnel the TVL® leads from the insertion site to the pulse generator pocket. It consists of the tunneler (Model LT-01), detachable RV/SVC (Model LT-RVC-01) and SQ (Model LT-SQC-01) cartridges which hold the leads in place during the tunneling procedure, and a detachable dissection tip (LT-DT-01). All parts of the tunneler are made of stainless steel.

E. High Voltage Y-Adapter Model AC-2481

The high voltage Y-adapter is for use during testing of defibrillation lead systems having more than two electrodes. It allows two defibrillation leads to be connected to a single polarity of the Model AC-2480 adapter block for the HVS®-02 cardiac electrophysiology device. The Y-Adapter consists of an acetal copolymer block with two nickel-plated brass connector posts which accept the pin connectors of the defibrillation leads. A silicone rubber insulated wire extending from the Y-Adapter block terminates in a connector pin for connection to the HVS adapter block.

F. Ventritex External Stimulator Adapter Model AC-CDT-EX

The Ventritex External Stimulator Adapter (VESA) connects an external stimulation source to Ventritex implantable cardioverter/defibrillators (ICD) models V-110, V-112, V-105 and V-115 for delivery of stimuli via an implanted lead system. The VESA is a stainless steel screw that is inserted into one of the high voltage ports of the pulse generator, allowing connection of an external stimulation source to the device.

G. TVL Lead System Accessory Kit Model AC-TVL

The TVL® Lead System Accessory Kit contains Stylets Models S-45-R, S-45-F, S-55-R, S-55-F, S-67-R, S-67-F, S-100-R, S-100-F, S-110-R, S-110-F; Suture Sleeves Models TV-1100 and TV-0800; Lead Caps Model TV-3201; Silicone Oil Model AC-0130; Introducers Models IN-8.5 and IN-11; DF-1 Receptacle Plugs Models AC-CDT-DP and RP-3201; Retention Screws Model AC-CDT-RS; Screwdrivers and Allen Wrenches Models AC-CDT-SD and AC-0121; Cap Screws Model AC-0111; and Setscrews Model AC-0101.

IV. Contraindications

Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Patients with a supraventricular tachyarrhythmia that is not suppressed with drug therapy and has a rate within the programmed tachyarrhythmia detection range since the device may detect the supraventricular tachyarrhythmia and deliver tachyarrhythmia therapy.

V. Warnings

- Use only battery-powered equipment when implanting and testing leads to avoid fibrillation caused by alternating current.
- Ground all line-powered equipment used near the patients to avoid fibrillation caused by alternating current.
- Insulate lead connector pins from potential leakage currents from line-powered equipment to avoid firillation caused by the leakage current.

VI. Precautions

The following precautions which apply to all TVL® Leads include the following:

- Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create

excessive strain at the insertion site as this may damage the lead.

- Do not grip the lead or the pulse generator with surgical instruments as this may damage the lead.

Use the same polarity evaluated during testing when connecting the leads to the pulse generator to ensure defibrillation efficacy.

If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.

If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior-posterior) and be sure that the external paddle is not positioned over the SQ patch.

The following precautions apply to the RV and SVC Leads:

- Do not severely bend or kink sylets or leads as this may damage the lead.

- Do not use excessive force or surgical instruments to insert a stylet into a lead as this may damage the lead.

- Withdraw the stylet after placing the lead to prevent potential malfunction of the lead.

- Use the correct suture sleeve for each lead to immobolize the lead and protect it against damage from ligatures.

The following precautions apply to the RV leads:

- Use ventricular transvenous leads with caution in patients with tricuspid valvular prostheses.

- Do not place the RV lead near another implanted lead to ensure sensing and defibrillation efficacy.

The following precautions apply to the SQ Leads:

- Do not place the SQ patch electrode over nerve tissue as this may cause nerve damage.

- Place the SQ patch with the conducting coil side facing the heart to ensure delivery of energy to the heart.

- Place sutures well outside the coil or in the area between the coils to avoid possible coil fracture.

- Do not fold, alter, or remove any portion of the patch as it may compromise electrode function or longevity.

VII. Alternative Practices and Procedures

Alternative therapies to the TVL® Lead System used in conjunction with a Ventritex Tiered Therapy Defibrillator are antiarrhythmic drug therapy and antiarrhythmia therapy surgery. Other commercially available automatic implantable cardioverter/defibrillator systems may also meet the needs of the patients with the indications described in Section II.

VIII. Marketing History

In November, 1993, Ventritex, Inc. began marketing the TVL® Lead System outside the United States. Approximately 55 TVL® lead systems were marketed in Italy, Spain, Sweden, Germany and the United Kingdom with no adverse effects reported. The system has not been removed from any of these countries for any reasons related to the safety and effectiveness of the device.

IX. Adverse Events

Observed Adverse Events Reported in More Than One Patient. Mean Duration of Exposure for All Patients Was 15.3 Months

The TVL Lead System clinical trial involved 311 patients with implanted systems and 4,766 cumulative implant months (mean implant duration = 15.3 months, range 2 days to 25.2 months).

Seventeen patients died during the course of this trial. None of the deaths were judged to be related to the implanted system.

Table 1 lists adverse events (AEs) reported from this clinical trial on a per patient and a per patient-month basis. The last column shows the expected time between events, i.e., the reciprocal of the AE/patient-month rate. Events that occurred in more than one patient are listed. A complication is defined as a clinical event with potential adverse effects that requires invasive intervention to treat or resolve. An observation is an event that does not require invasive intervention.

Table 1. Observed Adverse Events Reported in More Than One Patient Mean Duration of Exposure for All Patients Was 15.3 Months

	# Patients (n = 311)	% of Patients	# of AEs	AE/Pt-Mo (n = 4766)	Pt-Mos Between AEs
Observations					
Inappropriate therapy for AF, ST or SVT	73	23.50%	111	0.0200	42
Undersensing/poor R-waves	8	2.60%	10	0.0021	476
SVC lead migration	6	1.90%	6	0.0013	794
High defibrillation thresholds	5	1.60%	6	0.0013	794
Inappropriate therapy due to A-V or T-wave sensing	5	1.60%	5	0.0010	953
Elevated pacing thresholds	4	1.30%	4	0.0008	1191
Pocket swelling or soreness	4	1.30%	4	0.0008	1191
Bleeding/hematoma	2	0.60%	2	0.0004	2383
Pneumothorax	2	0.60%	2	0.0004	2383
Venous thrombosis	2	0.60%	2	0.0004	2383
Complications					
Infection	8	2.60%	9	0.0019	529
High defibrillation thresholds	6	1.90%	6	0.0013	794
Lead fracture or noise	5	1.60%	6	0.0013	794
RV lead dislodgement	2	0.60%	2	0.0004	2383

X. Summary of Studies

A. Electrical Testing

Electrical testing was performed by subjecting 10 leads of each type to electrical resistance testing and high voltage pulsing. The test results demonstrated the electrical integrity of the leads was within specifications when subjected to a large number of high voltage pulses.

B. Environmental Testing

Environmental testing was performed to determine the leads' resistance to a corrosive environment. Accelerated corrosion testing of 10 leads of each type was performed in saline heated to 85 degrees Centigrade (C). Visual inspection and resistance measurements indicated that the leads were corrosion resistant and qualified for human use. Pulse corrosion testing was performed on 10 leads of each type by delivering high voltage pulses into leads that had been submersed in saline heated to 85 degrees C. Dimensional inspection, electrical testing and durability testing (pull testing)demonstrated that the mechanical and electrical integrity of the leads after pulse corrosion testing was within specifications.

C. Mechanical Testing

1. Flex Testing

Fatigue testing of various sections of the leads (joints, conductor body, connector, and electrode) was performed to confirm the ability of the leads to withstand flexing that simulates *in vivo* conditions with no adverse affects on mechanical or electrical integrity. The number of samples tested ranged from 8 to 30. The RV lead sections, SVC lead sections, and SQ patch distal joint were flexed ±10 degrees in saline heated to 37 degrees C. The SQ patch electrode was flexed ±15

degrees in air at 25 degrees C. Visual and electrical testing confirmed that the mechanical and electrical integrity of the leads after flex testing met the design specifications.

2. Vibration Testing

Vibration testing was performed with 10 leads (of each type) in sealed packages. Visual, dimensional and electrical testing confirmed that after vibration testing, the leads met the acceptance criteria.

3. Durability Testing

Nondestructive lead durability testing (pull testing) was performed by applying a 1.1 lb_f axial tensile load to 10 leads of each type. Visual, dimensional and electrical testing confirmed acceptable mechanical and electrical lead integrity after durability testing.

4. Thermal Cycling

Thermal cycling was performed by subjecting 10 leads of each type to multiple cycles between -20 degrees C and +75 degrees C. Visual, dimensional and electrical testing confirmed acceptable mechanical and electrical lead integrity after temperature cycling.

5. Standards Compatibility Testing

Testing was performed to verify conformance to the two relevant international connector standards (IS-1 sensing/pacing lead connector and DF-1 defibrillation lead connector). Tests included maximum insertion and withdrawal forces, current leakage, electrical impedance between conducting parts, and deformation due to setscrew and grip zone forces. Conformance to the 2 standards was verified by demonstrating compliance with the dimensional and performance requirements.

6. Lead Tunneler

The tunneling tool was qualified through verification of compliance of critical dimensions to drawing requirements, demonstration of mechanical integrity through tension, compression and bending testing, and evaluation of lead/cartridge insertion and removal forces. The number of samples tested ranged from 3 to 5. All samples were within specifications.

D. Life Testing

Ten leads of each type were subjected to life testing to confirm the long-term reliability of the leads when exposed to greater than expected stresses (current pulses, flexing, and temperature). The TVL® leads demonstrated long-term reliability in the high stress, simulated *in vivo* environment.

Number	Lead System Used
282	Transvenous leads only
27	Transvenous lead+ SQ patch
1	RV lead + SQ patch
1	RV lead + SVC x 2

The population was predominately male (234, 75% with an average age of 62.7 years. The arrhythmia diagnosis was:

Percent	Arrhythmia Diagnosis
19%	ventricular fibrillation (VF)
55%	ventricular tachycardia (VT)
26%	both VF and VT

Coronary artery disease was the primary disease process in 75% of the patients, and the average reported ejection fraction was 33%. The majority of the patients (66%) had been on an antiarrhythmic medication at some point during their enrollment in the clinical investigation.

2. Methods

Patients were seen for follow-up every two months during the first year post implant and every three months thereafter. If the patient's condition permitted, at least one test was performed with an intentional programmed ineffective first therapy to evaluate arrhythmia detection/ redetection. Conversion efficacy and arrhythmia detection/redetection times were collected.

Lead stability over time was assessed through evaluation of trend graphs. Pacing lead impedance, pacing threshold, R-wave measurements, and defibrillation lead impedance were assessed over the course of the clinical investigation.

3. Results

The study began on November 1, 1993 and data were collected through December 8, 1995. Thus, the duration of the study was approximately 25 months. The average enrollment duration for the patient population was 466 days (15.3 months), with a range of 2 days to 767 days. The duration of implantation was:

Months	Number of patients
6	302
12	219

The TVL System was successfully implanted in 307 of 311 (97%) of the patients. The transvenous leads only were initially implanted in 282 of 311 (91%) patients. The average ± standard deviation defibrillation energy requirements (DER, step-down plus reconfirmation method) was 15.2 ± 6.6 Joules with a corresponding voltage of 472 ± 108 volts. DER for the historical patch control group was 13.6 ± 6.6 Joules.

There were 17 patient deaths during the study. All were reviewed and classified by an independent committee. Five of the deaths were classified as sudden (1.6 percent, 5 of 311), 8 were classified as non-sudden cardiac (2.6 percent 8 of 311),

91

and 4 were non-cardiac. (1.3 percent, 4 of 311). None of the deaths were judged to be device related.

Table 2. Summary of Survival Results
Percent surviving at 1 yr [95 percent confidence interval] by Cutler-Ederer life table analysis

	TVL patients (N=311)	Patch historical control patients (N=1,188)
Survival from sudden death to 1 yr	98.1% [96.5-99.6%]	95.6% [94.3-96.9%]
Perioperative survival	99.4% [98.5-100%]	96.7% [95.5-98.0%]
All-cause survival to 1 yr	95.2% [92.7-97.6%]	89.7% [87.7-91.7%]

Table 3. Conversion efficacy and arrhythmia detection/redetection times
Mean and [95 percent confidence interval] by binomial probabililty methods

	TVL patients (N=311)	Patch historical control patients (N=1,188)
Conversion - Induced episodes, %	98.8% [98.3-99.1%] (N=2,142)	99.3% [99.1-99.5%] (N=7,158)
Conversion - Spontaneous episodes, %	100% [99.9-100%] (N=3,222)	99.9% [99.9-100%] (N=34,520)
Detection times, mean ± std dev	4.5 ±1.7 sec	4.2 ±1.4 sec
Redetection times, mean ± std dev	2.2 ±0.9 sec	2.2 ±0.98sec

4. Complications and Observations

Please see the ADVERSE EVENTS section of the product label.

5. Explants

Five patients (1.6 percent had leads explanted for suspected malfunction (5 RV-1101 leads and 1 SV-1101 lead). No defects or damage could be found with 2 of the RV leads and the SVC lead. Of the other 3 RV leads, one exhibited clavicular crush syndrome, one had evidence of mechanical abrasion from the pulse generator can, and one had an inner insulation tear. The insulation was damaged during the repositioning procedure of 1 (0.3 percent) additional RV lead). Eight lead systems (2.6 percent) were explanted due to infection; four of the patients subsequently received new TVL lead systems.

XI. Conclusions Drawn from the Studies

The results of the nonclinical (laboratory and animal) studies and the clinical study of the TVL® Lead System demonstrate that the system, including all of the associated components, performs according to its design intent and is safe and effective for use. The primary endpoint of one-year survival from sudden death plus perioperative mortality was 98.1 percent in the TVL® study population, compared to 95.6 percent in the historical control group. One-year survival from death from all causes was 95.2 percent in the TVL® study population and 89.7 percent in the historical control group. For all

comparisons, the TVL® study population had statistically equivalent or better survival.

XII. Panel Recommendations

Pursuant to section 515(c)(2) of the Food, Drug and Cosmetic Act (the Act) as amended by the Safe Medical Devices Act of 1990, the PMA application was not referred to the Circulatory System Devices panel, an FDA advisory panel, for review and recommendation because the information in the PMA application substantially duplicates information previously reviewed by this panel.

XIII. FDA Decision

FDA found Ventritex, Inc's facilities in compliance with the Device Good Manufacturing Practices regulation (21 CFR part 820).

After review of the data contained within the PMA application and amendments for the Ventritex TVL® Lead System, FDA recommended approval of the application. FDA requested the following: final copies of the device labeling be placed in a specific format, the technical manual be revised to state that the TVL® Leads are for use as part of a system, and an identifying mark be placed on the package label of the TVL® Leads which distinguishes nonthoracotomy leads from thoracotomy leads.

XIV. Approval Specifications

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician with appropriate training.

Preface

About This Manual

This manual describes the characteristics and implantation of the Ventritex® TVL® Lead System.

For information about the pulse generator, its settings, parameters, etc., refer to the appropriate defibrillator physician's manual. For information on setting up and using the HVS-02 electrophysiology device, see the *Ventritex HVS-O2 Cardiac Electrophysiology Device Operator's Manual*

Using This Manual

This manual uses certain conventions to differentiate between actions to be taken and information or explanations pertaining to those actions.

1. **Numbered paragraphs describe steps to be taken.**

   Paragraphs like this one provide explanations of the action called for by the step above it as well as additional information that might be useful at that point in the procedure.

Technical Assistance

Ventritex has professional staff available 24 hours a day at 408-738-4883 or toll-free in the USA and Canada at 800-733-3455.

Ventritex Patents

The Ventritex TVL Lead System is covered by the following patents: 5,266,260; 5,385,578; and 5,439, 485.

121

Device Description

The Ventritex® TVL® Lead System consists of a transvenous, tined, right ventricular (RV) lead, a transvenous superior vena cava (SVC) lead, and a subcutaneous (SQ) patch lead. The SQ patch can deliver cardioversion/ defibrillation shocks when reliable arrhythmia conversion cannot be obtained using the transvenous leads alone or when an alternative configuration of leads is desired.

Indications

The TVL Lead System is indicated for use with commercially available pulse generators with which it has been tested. The TVL Lead System is a transvenous defibrillation lead system and is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with an acute myocardial infarction or have ventricular tachyarrhythmias. In addition, the TVL Lead System can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the connected pulse generator provide therapy back-up in the event that the arrhythmia accelerates.

Contraindications

The TVL Lead System is contraindicated in the following:

- Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.
- Patients with a supraventricular tachyarrhythmia that is not suppressed with drug therapy and has a rate within the programmed tachyarrhythmia detection range, since the device may detect the supraventricular tachyarrhythmia and deliver tachyarrhythmia therapy.

123

Warnings

- Use only battery-powered equipment when implanting and testing leads to avoid fibrillation caused by alternating current.
- Ground all line-powered equipment used near the patient to avoid fibrillation caused by alternating current.
- Insulate lead connector pins from potential leakage currents from line-powered equipment to avoid fibrillation caused by the leakage current.

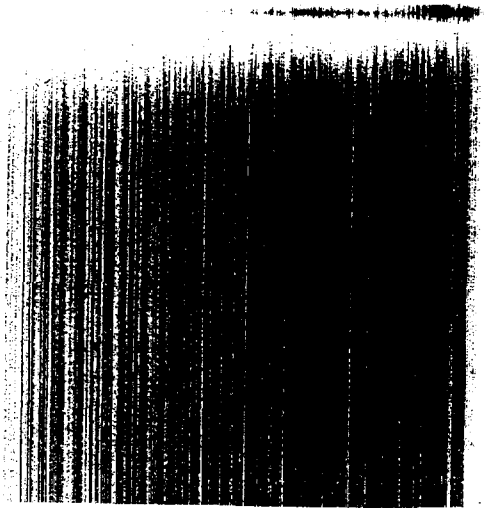
Precautions

Precautions for All TVL Leads

- Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create excessive strain at the insertion site as this may damage the lead.
- Do not grip the lead or the pulse generator with surgical instruments as this may damage the lead.
- Use the same polarity evaluated during testing when connecting the leads to the pulse generator to ensure defibrillation efficacy.
- If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.
- If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior-posterior) and be sure that the external paddle is not positioned over the SQ patch.
- Do not resterilize as doing so may damage the leads.

Precautions for RV and SVC Leads

- Do not severely bend or kink stylets or leads as this may damage the lead.
- Do not use excessive force or surgical instruments to insert a stylet into a lead as this may damage the lead.
- Withdraw the stylet after placing the lead to prevent potential malfunction of the lead.
- Use the correct suture sleeve for each lead to immobilize the lead and protect it against damage from ligatures.



Precautions for RV Leads

- Use ventricular transvenous leads with caution in patients with tricuspid valvular prostheses.
- Do not place the RV lead near another implanted lead to ensure sensing and defibrillation efficacy.

Precautions for SQ Leads

- Do not place the SQ patch electrode over nerve tissue as this may cause nerve damage.
- Place the SQ patch with the conducting coil side facing the heart to ensure delivery of energy to the heart.
- Place sutures well outside the coil or in the area between the coils to avoid possible coil fracture.
- Do not fold, alter, or remove any portion of the patch as it may compromise electrode function or longevity.
- The SQ patch lead is not intended for epicardial or pericardial placement.

Adverse Events

Observed Adverse Events Reported in More Than One Patient

Mean Duration of Exposure for All Patients Was 15.3 Months

The TVL Lead System clinical trial involved 311 patients with implanted systems and 4,766 cumulative implant months (mean implant duration = 15.3 months, range 2 days to 25.2 months).

Seventeen patients died during the course of this trial. None of the deaths were judged to be related to the implanted system.

Table 1 lists adverse events (AEs) reported from this clinical trial on a per patient and a per patient-month basis. The last column shows the expected time between events, i.e., the reciprocal of the AE/patient-month rate. Events that occurred in more than one patient are listed. A complication is defined as a clinical event with potential adverse effects that requires invasive intervention to treat or resolve. An observation is an event that does not require invasive intervention.

125

Observed Adverse Events Reported in More Than One Patient (Cont'd)

Mean Duration of Exposure for All Patients Was 15.3 Months

	# Patients (n = 311)	% of Patients	# of AEs	AE/Pt-Mo (n = 4766)	Pt-Mos Between AEs
Observations					
Inappropriate therapy for AF, ST or SVT	73	23.5%	111	0.0200	42
Undersensing/poor R-waves	8	2.6%	10	0.0021	476
SVC lead migration	6	1.9%	6	0.0013	794
High defibrillation thresholds	5	1.6%	6	0.0013	794
Inappropriate therapy due to A-V or T-wave sensing	5	1.6%	5	0.0010	953
Elevated pacing thresholds	4	1.3%	4	0.0008	1191
Pocket swelling or soreness	4	1.3%	4	0.0008	1191
Bleeding/hematoma	2	0.6%	2	0.0004	2383
Pneumothorax	2	0.6%	2	0.0004	2383
Venous thrombosis	2	0.6%	2	0.0004	2383
Complications					
Infection	8	2.6%	9	0.0019	529
High defibrillation thresholds	6	1.9%	6	0.0013	794
Lead fracture or noise	5	1.6%	6	0.0013	794
RV lead dislodgement	2	0.6%	2	0.0004	2383

Table 1. Observed adverse events

Potential Adverse Events

Possible adverse events associated with the use of transvenous lead systems include, but are not limited to, those summarized in Table 2.

Refer to the appropriate pulse generator physician's manual for additional complications and precautions specific to the pulse generator.

Event	Possible Effects
Displacement of lead insulation, connector fracture, or poor connection to the pulse generator	Intermittent or continuous loss of sensing, possibly resulting in non-detection of arrhythmia; oversensing of artifact, possibly causing inappropriate delivery of therapy from the pulse generator; intermittent or continuous loss of defibrillation, cardioversion, or pacing therapy; and possible muscle or nerve stimulation in the pocket area
Electrode fracture	Intermittent or continuous loss of cardioversion/defibrillation therapy, sensing, or pacing therapies
Cardiac perforation	Intermittent or continuous loss of sensing, cardiac tamponade, hemorrhage, pneumothorax, or loss of contractility
Venous perforation	Acute hemorrhage (may not be readily apparent), hemothorax, pneumothorax, or cardiac tamponade
Myocardial irritability	Premature ventricular contractions, supraventricular and ventricular tachyarrhythmias, postoperative heart failure
Transvenous implantation procedure	Air embolism
Chronic (> 3 months) implantation	Venous thrombosis and/or obstruction, tissue necrosis, skin erosion, tricuspid valve dysfunction, chronic mechanical stimulation of the heart
Contamination	Infection requiring removal of lead system, pulse generator, or both
Post-shock rhythm disturbances	Post-shock bradycardia or supraventricular arrhythmias, conduction disturbances
Threshold elevation or exit block	Loss of efficacy of defibrillation, cardioversion, or pacing therapy
Shunting or insulating of current during defibrillation with internal or external paddles	Increased external defibrillation energy and/or repositioning of paddles required

Table 2. Potential complications

127

Clinical Studies

A multicenter, prospective, historical control clinical investigation in 311 patients at 30 centers in the United States and Europe compared the TVL Lead System to the patch lead system. The primary endpoint was one-year survival from sudden death (including perioperative mortality). Secondary endpoints were perioperative mortality and one-year survival from all-cause mortality.

Most (282) patients received the transvenous system (RV/SVC) alone, 27 patients received the transvenous system and an SQ patch, one received an RV lead and an SQ patch, one patient received one RV and two SVC leads.

The TVL Lead System was tested with Cadence V-100, V-110, and V-112 as well as Cadet V-115 and V-105 pulse generators.

The patients were seen for follow-up every two months during the first year postimplant and every three months thereafter. If the patient's condition allowed, at least one test was performed with an intentionally-programmed ineffective first therapy to evaluate arrhythmia redetection. Conversion efficacy and arrhythmia detection/redetection time were collected in addition to the survival data.

The historical control population included patients from the original Cadence IDE study who received primary epicardial defibrillation patch leads without concomitant surgery.

	TVL Population	Historical Control
Number of patients	311	1188
Primary endpoint—sudden death plus perioperative survival	98.1% [96.5%–99.6%][1]	95.6% [94.3%–96.9%]
Secondary endpoint—perioperative survival	99.4% [98.5%–100%]	96.7% [95.5%–98.0%]
Secondary endpoint—survival from death from all causes	95.2% [92.7%–97.6%]	89.7% [87.7%–91.7%]

Table 3. Summary of efficacy results (1-year survival)

1. All numbers in brackets represent 95% confidence interval (Cutler-Ederer life table analysis).

	TVL Population (N = 311)	Historical Control (N = 1188)
Conversion—induced episodes, %	98.8% (N = 2142) [98.3%–99.1%][1]	99.3% (N = 7158) [99.1%–99.5%][1]
Conversion—spontaneous episodes, %	100% (N = 3222) [99.9%–100%][1]	99.99% (N = 34520) [99.98%–100%][1]
Detection times, mean ± standard deviation	4.5 seconds ± 1.7 (N = 305)	4.2 seconds ± 1.4 (N = 94)
Redetection times, mean ± standard deviation	2.2 seconds ± 0.9 (N = 305)	2.2 seconds ± 0.8 (N = 94)

Table 4. Conversion efficacy and arrhythmia detection/redetection times

1. Numbers in brackets represent 95% confidence interval (binomial probability methods).

129